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Evaluation of Oxygen Concentrators and Chemical Oxygen Generators at Altitude and Temperature Extremes

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Supplemental oxygen can be lifesaving in emergency situations, although the burden of providing oxygen during transport and in remote areas is substantial in cost, transport, and materials. Oxygen cylinders are heavy and present a number of potential hazards including fire and projectile risks. Liquid oxygen systems provide a large amount of gas with a smaller footprint but are heavy, exhaust gas over time, and present a burn risk if handled improperly. Additionally, the output of both of these oxygen systems is finite and requires refilling, which presents logistical issues in far forward military operations. Simpler, lighter, and longer lasting oxygen delivery systems are needed for military and mass casualty operations. As possible materiel solutions, we evaluated portable oxygen concentrators (POCs) and chemical oxygen generators at altitude and temperature extremes. Understanding performance of these devices under deployed conditions is crucial to safe and effective use. POCs and chemical oxygen generators have been proposed as alternatives to liquid and pressurized gaseous oxygen systems in far forward military operations and in disaster and mass casualty scenarios. The austere environments in which the devices may be deployed may have an effect on performance. Storage at extremely cold temperatures had the greatest negative effect on the performance of the POCs. Allowing additional time for the devices to acclimate to room temperature before startup may improve device performance. POCs should not be operated at altitudes above that stated in the operator's manual.

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1.0 SUMMARY

Supplemental oxygen can be lifesaving in emergency situations, although the burden of providing oxygen during transport and in remote areas is substantial in cost, transport, and materials. Oxygen cylinders are heavy and present a number of potential hazards including fire and projectile risks. Liquid oxygen systems provide a large amount of gas with a smaller footprint but are heavy, exhaust gas over time, and present a burn risk if handled improperly. Additionally, the output of both of these oxygen systems is finite and requires refilling, which presents logistical issues in far forward military operations. Simpler, lighter, and longer lasting oxygen delivery systems are needed for military and mass casualty operations. As possible materiel solutions, we evaluated portable oxygen concentrators (POCs) and chemical oxygen generators at altitude and temperature extremes. Understanding performance of these devices under deployed conditions is crucial to safe and effective use. POCs and chemical oxygen generators have been proposed as alternatives to liquid and pressurized gaseous oxygen systems in far forward military operations and in disaster and mass casualty scenarios. The austere environments in which the devices may be deployed may have an effect on performance. Storage at extremely cold temperatures had the greatest negative effect on the performance of the POCs. Allowing additional time for the devices to acclimate to room temperature before startup may improve device performance. POCs should not be operated at altitudes above that stated in the operator's manual.

2.0 BACKGROUND

Supplemental oxygen can be lifesaving in emergency situations, although the burden of providing oxygen during transport and in remote areas is substantial in cost, transport, and materials. Oxygen cylinders are heavy and present a number of potential hazards including fire and projectile risks. Liquid oxygen systems provide a large amount of gas with a smaller footprint but are heavy, exhaust gas over time, and present a burn risk if handled improperly. Additionally, the output of both of these oxygen systems is finite and requires refilling, which presents logistical issues in far forward military operations. Simpler, lighter, and longer lasting oxygen delivery systems are needed for military and mass casualty operations. As possible materiel solutions, we evaluated portable oxygen concentrators (POCs) and chemical oxygen generators (COGs) at altitude and temperature extremes. Understanding performance of these devices under deployed conditions is crucial to safe and effective use.

3.0 METHODS

We evaluated three commercially available POCs—Eclipse 3 and SAROS (Chart Industries, Ball Ground, GA) and iGo (DeVilbiss Healthcare, Somerset, PA)—and three COGs— O_2PAK™ (Pacific Precision Products, Irvine, CA), TraumAid-26 (HABCO Industries, Blastonbury, CT), and BUDI Oxygen Bag (BOB) (Green Dot Systems, Miami, FL)—in a laboratory setting. The devices were evaluated at sea level and at altitudes of 8,000, 16,000, and 22,000 feet corresponding to barometric pressures of 760, 565, 412, and 321 mmHg in a man-rated altitude chamber at Wright-Patterson Air Force Base, Dayton, OH. An altitude of 8,000 feet was chosen to represent a simulated cabin altitude during Critical Care Air Transport Team flight. An altitude of 22,000 feet was chosen to represent the upper limit of crew functionality in

the case of aircraft decompression and conditions for Special Forces mission requirements. The devices were also evaluated after storage for 24 hours at temperature extremes of -35°C (-31°F) and 60°C (140°F) in an altitude/environmental chamber at the University of Cincinnati. The devices were allowed to acclimate to room temperature for 30 minutes after placement outside the chamber before measurements were made. Room temperature was 21°C (70°F).

COG flow output was obtained by attaching the oxygen tubing to the device and to a Fleisch pneumotachograph (Series 4700, Hans Rudolph, Shawnee, KS). Liter flow, total oxygen volume, and duration of operation were measured continuously after activation of the devices until flow ceased. Oxygen concentration was continuously measured with a fast laser diode oxygen analyzer (O2CAP, Oxigraf, Inc., Mountain View, CA) throughout the duration of operation. The output generated from the COGs was analyzed by a gas mass spectrometer (QGA model HAS 301, Hiden Analytical, Livonia, MI) to determine the gas composition. Surface temperature of the COGs was measured intermittently throughout the duration of operation with a non-contact infrared thermometer (62 Max, Fluke Corporation, Everett, WA).

Measurements of flow, volume, and fraction of inspired oxygen (FiO_2) were accomplished by attaching oxygen tubing to the outlet of the POCs and to the inlet of an oxygen concentrator tester (Hans Rudolph, Shawnee, KS) and running the device in either continuous flow or bolus mode. The concentrator tester has the ability to provide negative pressure to simulate inspiratory effort, which triggers the concentrator to deliver a predetermined bolus of oxygen. Concentrators were tested at 1, 2, and 3 Lpm continuous flow and throughout the range of bolus volumes with each device at respiratory rates of 20 and 30 breaths/min with each bolus setting. Data were recorded every 100 ms with continuous flow mode and breath to breath in bolus mode. Concentrators were allowed 1 minute of stabilization and a minimum of 1 minute of data was collected at each setting.

Flow and volume accuracy was determined by comparing the measured values to the device specifications detailed in the operator's manual of the Eclipse and SAROS. The iGo operator's manual did not report an accuracy range for flow and bolus volume, so we used the ranges documented for the other two devices. Reported flow accuracy was ±10% or 200 mL/min, whichever was larger. Bolus volume accuracy was reported as ±15% of the set volume. FiO_2 accuracy range was determined by the documented range in the operator's manual for each device. The reported FiO_2 range was 90% ± 3% for the Eclipse, 91% ± 3% with the iGo, and 93% ± 3% with the SAROS. Additionally, battery life of the POCs was evaluated at room temperature after charging for 24 hours, using continuous flow at 3 Lpm and the highest pulse dose setting at a respiratory rate of 30 bpm. Two devices of each model were evaluated and all tests with each device were accomplished a minimum of two times. Data were continuously recorded to a computer for later analysis.

3.1 POCs

The POCs evaluated in this study were chosen because each produced the highest commercially available continuous flow output and bolus size. All the devices weighed less than 20 pounds. The Eclipse 3 and iGo can either be carried via handle or placed in a wheeled cart for transport. A harness that attaches to the SAROS that includes a shoulder strap provides a hands-free method in which to transport the device. Table 1 shows the specifications for the concentrators evaluated in this study.

Table 1. Concentrator Specifications

Specification	Eclipse 3	SAROS	iGo
Size (H x W x D) (in)	19.3 x 12.3 x 7.1	26.8 (L); 4.375 (diameter)	15 x 11 x 8
Weight with battery (lb)	17.4	12.25	19.0
Continuous Flow Settings (Lpm)	0.5 - 3.0 (0.5-Lpm increments)	1.0 – 3.0 (1-Lpm increments)	1.0 – 3.0 (1-Lpm increments)
Pulse Dose Settings (mL)	16 – 96, 128, 160, 192	16 – 96 (16-mL increments)	14 – 84 (14-mL increments)
O_2 Concentration (%)	90 ± 3	93 ± 3	91 ± 3
AC/DC Operation	Yes	Yes	Yes
Battery Life (h)	1.3 – 5.4	0.5 – 1.2	1.6 – 5.4
Storage Temperature (°C)	-20 to 60	-20 to 60	-20 to 60
Operating Temperature (°C)	10 to 40	0 to 43	5 to 40
Altitude Range (ft)	0 – 13,123	0 – 18,000	0 – 13,123

AC = alternating current; D = depth; DC = direct current; H = height; L = length; W = width.

3.2 COGs

Current COGs typically contain one or more of the following solid compounds: sodium chlorate, sodium perchlorate, potassium superoxide, or peroxide species' sodium percarbonate or percarbamide peroxide [1]. When combined with a catalyst, the resulting chemical reaction releases oxygen and produces heat. The COGs evaluated in this study are the O_2PAK, TraumAid, and BOB.

3.2.1 O_2PAK. The main ingredient in the O_2PAK is sodium chlorate in addition to small quantities of disodium peroxide, disodium oxide, mica, magnesium, sodium perchlorate, glaspowder, and zinc peroxide. The device is cylindrical, 9.8 inches in height and 4.0 inches in diameter, weighing 3.0 pounds [2]. The device is self-contained, sealed, and internally insulated and is supplied with a nylon cover for further insulation. A pin attached to a wire is pulled to activate the device. Oxygen begins to flow within seconds of activation. The O_2PAK has a small flow indicator at the end of the outlet tubing where oxygen tubing is attached and also connects to a nasal cannula or simple mask for patient use. Cost of the device is $675 each.

3.2.2 TraumAid. The main ingredient in the TraumAid is sodium perchlorate with smaller quantities of iron powder, manganese dioxide, and mica. Similar to the O_2PAK, the device is cylindrical, 8.2 inches in height and 3.5 inches in diameter, weighing 2.3 pound [3]. The device is self-contained, sealed, and internally insulated and may be fitted with an optional nylon cover for additional insulation. The device has two pins that must be pulled to initiate the reaction process. Oxygen flow begins seconds after activation. As with the O_2PAK, oxygen tubing is attached from the device outlet to a nasal cannula or simple mask for patient use. The cost of the device is $895 each.

3.2.3 BOB. The BOB system requires the user to add ingredients to a plastic bag to initiate oxygen production. The reusable bag and chemicals are supplied as a kit. The user places premeasured sodium percarbonate and manganese into the bag, adds 450 mL tap water, swirls the bag to mix, places the top on the bag, and attaches oxygen tubing from the outlet in the top to a nasal cannula or simple mask for use [4]. Oxygen flow begins several minutes after mixing the chemicals. The top of the device contains desiccant consisting of silica beads to absorb excess

moisture as the gas exists the bag. The cost for a single device kit is $163; the kit consists of one reusable bag and chemicals for two separate runs. A refill kit consisting of enough dry chemicals to run four reactions costs $50.

4.0 RESULTS

4.1 POCs

The mean FiO_2 with the Eclipse was within the manufacturer-stated range during all altitudes and temperatures in continuous flow mode and at all altitudes in bolus mode, but fell to <87% at bolus volumes of 128, 164, and 192 mL at both temperature extremes. Figure 1 shows the ranges and mean FiO_2 with the 192-mL bolus setting at a respiratory rate of 30 at all test conditions. The FiO_2 difference from room temperature was statistically significant ($p<0.0001$). Delivered FiO_2 was higher at altitude than at sea level, especially with the bolus volumes of 64 mL and greater. Using the 2-Lpm continuous flow setting, the mean flow was 1.7 Lpm at all three altitudes, which was slightly below the accuracy range of 1.8 – 2.2 Lpm. All continuous flow settings were within the accuracy range at temperature extremes. In bolus mode at the 128-mL and 160-mL settings at a respiratory rate of 30 and 192 mL at respiratory rates of 20 and 30, at all conditions the measured bolus volumes were less than the reported accuracy range by 5 – 45%.

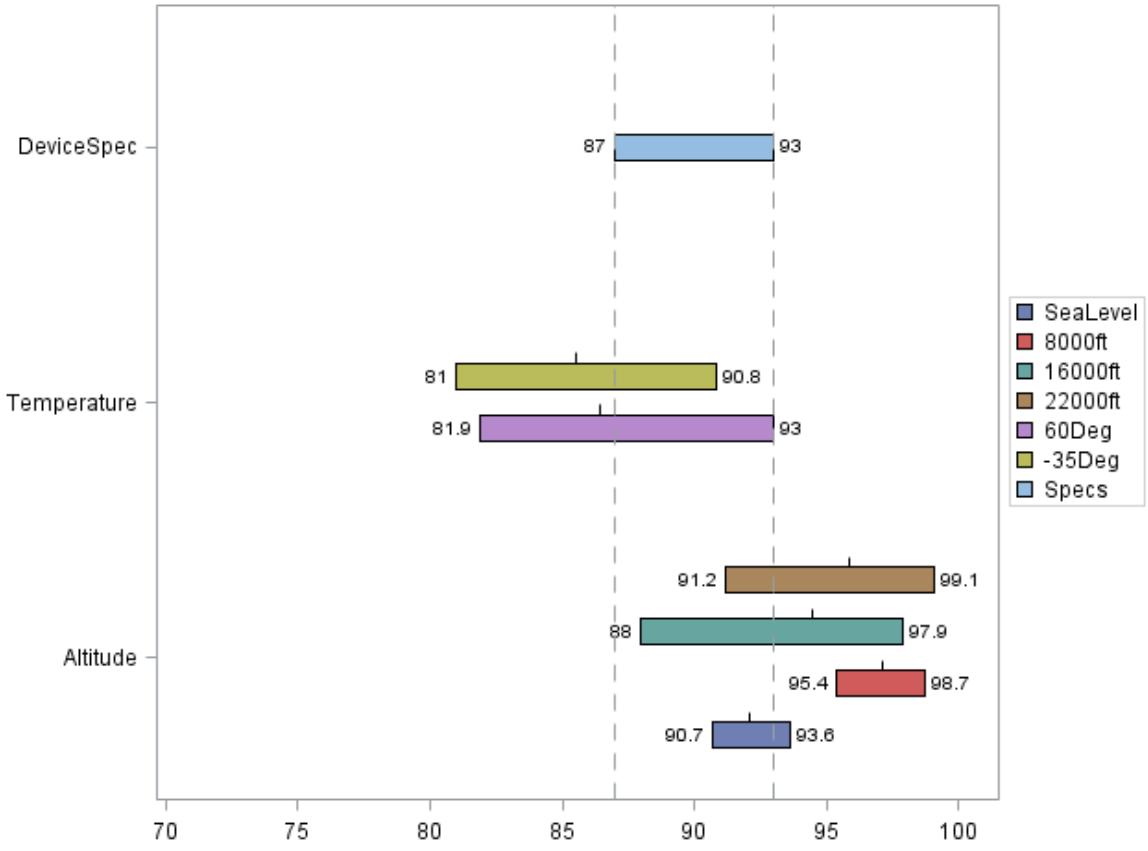

Figure 1. Range and mean FiO_2 on the 192-mL bolus setting with the Eclipse at a respiratory rate of 30 during all test conditions

The mean FiO_2 with the SAROS was within the specified range at all altitudes and temperature extremes in both continuous flow and bolus modes with the exception of 3-Lpm continuous flow after storage at -35°C (88% ± 3%) and 96-mL bolus modes after storage at both temperature extremes (88% ± 4%). Figure 2 shows the ranges and mean FiO_2 at the 96-mL bolus setting at a respiratory rate of 30 at all test conditions. The differences from room temperature values were not statistically significant ($p>0.05$). In all continuous flow settings the SAROS liter flows were less than the reported accuracy range by 0.1 – 0.2 Lpm after storage at -35°C and at all altitudes using the 2-Lpm setting and at 16,000 and 22,000 feet using the 1-Lpm setting. Flow accuracy was within specifications at sea level and after storage at 60°C. Pulsed dose volumes were 0.1 – 0.4 mL less than the stated accuracy at 16,000 and 22,000 feet using the 16-mL setting with respiratory rates of 20 and 30 bpm and after storage at -35°C using the 16-mL setting at a respiratory rate of 20 bpm. All other bolus volumes were within specifications.

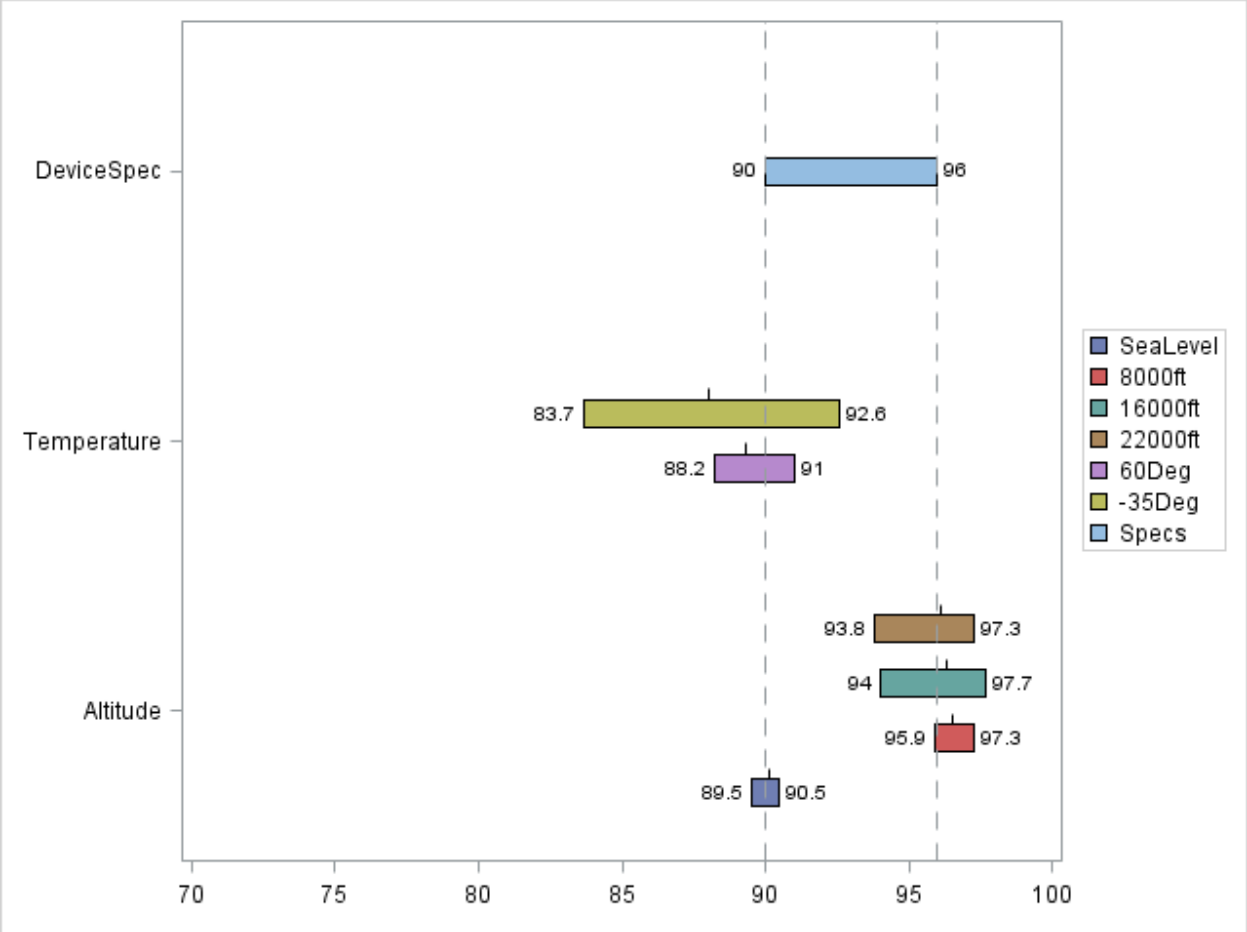

Figure 2. Range and mean FiO_2 at the 96-mL bolus setting with the SAROS at a respiratory rate of 30 during all test conditions

The iGo produced a mean FiO_2 that was within the specified range in both continuous flow and bolus modes at sea level and 8,000 feet and after storage at 60°C. At 16,000 feet the FiO_2 fell to 81% in continuous flow mode and failed to operate in bolus mode. After storage at -35°C, the FiO_2 range was 73% ± 0.3% – 78% ± 9% in continuous flow mode. The difference from room temperature measurements was statistically significant ($p<0.01$). Figure 3 shows the range and mean FiO_2 at the 3-Lpm continuous flow setting at all test conditions. In continuous flow mode at the 2-Lpm setting after storage at 60°C and at the 3-Lpm setting after storage at -35°C, measured flow rate was less than specifications by 0.1 Lpm and 0.5 Lpm, respectively. All bolus modes at sea level, 8,000 feet, and after storage at both temperature extremes were within the specified accuracy range.

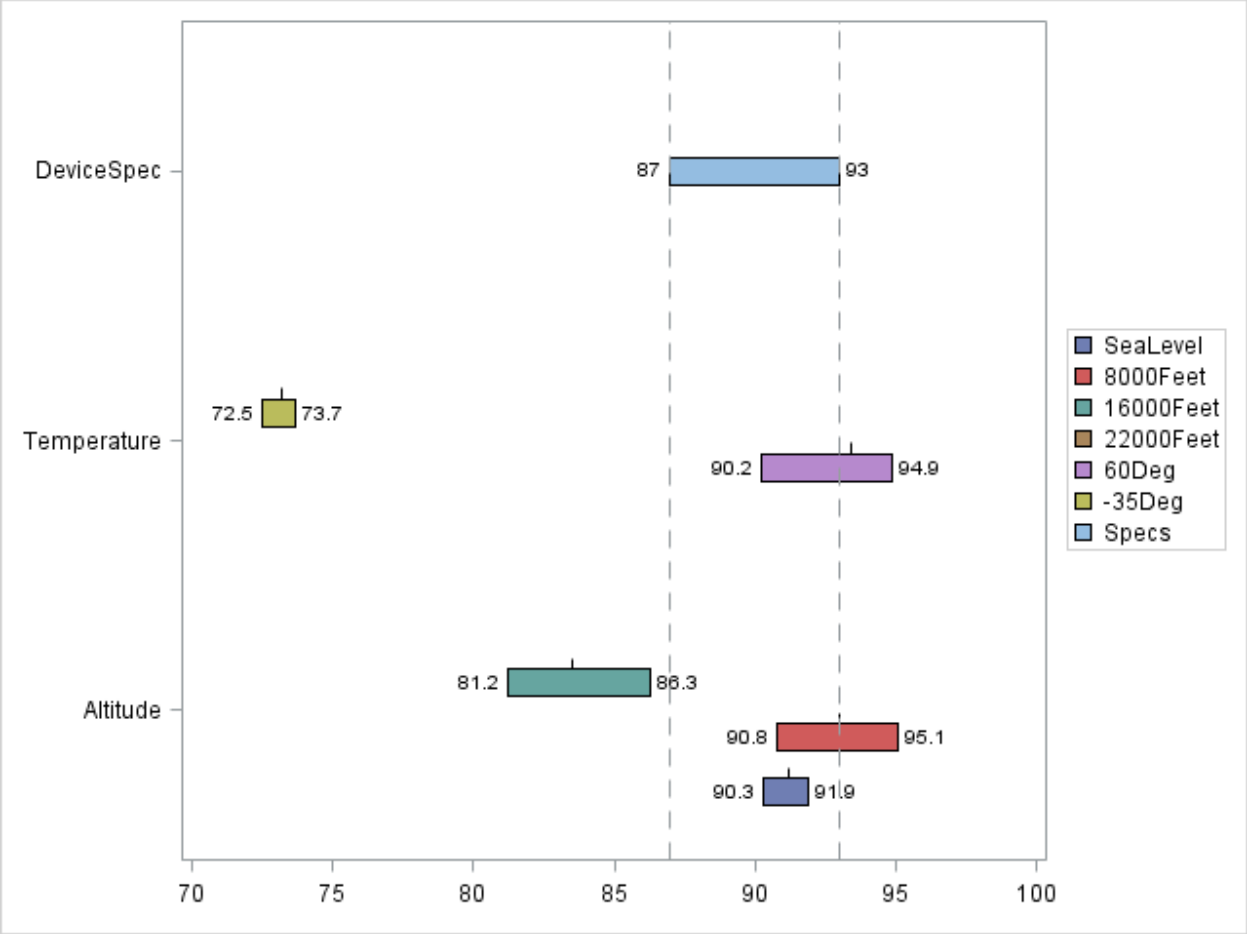

Figure 3. Range and mean FiO_2 at the 3-Lpm continuous flow setting with the iGo during all test conditions

Battery life varied widely between the concentrators. At the highest pulse dose setting (192 mL with the Eclipse, 96 with the SAROS, and 84 mL with the iGo) using a respiratory rate of 30 and 3-Lpm continuous flow settings, respectively, mean (standard deviation [SD]) battery life in minutes was 75.5 ± 0.6 and 76.0 ± 0.8 with the Eclipse, 57.0 ± 4.1 and 34.0 ± 2.2 with the SAROS, and 184.5 ± 0.7 and 108.5 ± 2.1 with the iGo.

One of each of the POCs was rendered inoperable after storage at -35°C. The Eclipse and iGo would start, but the membrane pads to make mode and flow adjustments would not respond and the SAROS would not start. These devices were reevaluated after having been at room temperature for 24 hours, but the problems remained and were permanent.

4.2 COGs

As compared to sea level at room temperature, flow rate, duration of operation, and total volume of oxygen produced varied widely between devices and within the same devices when exposed to temperature extremes and increased altitude. The inter-device variability was greatest with the BOB at all conditions, but this device was least affected by temperature extremes. As compared to room temperature measurements at sea level, mean liter flow and total oxygen volume increased with each increase in altitude with all COGs (Table 2). Duration of operation did not markedly change with the O_2PAK and TraumAid with changes in altitude and was inconsistent with the BOB. Mean oxygen concentration was 99.9%, 95% confidence interval (CI) [99.87%, 99.94%] with the O_2PAK; 99.9%, 95% CI [99.89%, 99.96%] with the TraumAid; and 80.9%, 95% CI [80.16%, 81.39%] with the BOB. The oxygen concentration measurements started when flow began and continued until flow ceased.

Table 2. Mean Liter Flow and Mean Total Oxygen with Percent Increase from Sea Level Measurements with the COGs at Each Altitude

System	Sea Level		8,000 ft		16,000 ft		22,000 ft	
	Liter Flow (Lpm)	Volume (L)	Liter Flow (% increase) (Lpm)	Volume (% increase) (L)	Liter Flow (% increase) (Lpm)	Volume (% increase) (L)	Liter Flow (% increase) (Lpm)	Volume (% increase) (L)
O_2PAK	6.5	181.31	7.6 (17)	220.5 (22)	10.5 (62)	301.0 (66)	14.4 (122)	421.3 (132)
TraumAid	5.6	139.2	5.6 (0)	152.9 (10)	8.8 (57)	222.2 (60)	9.9 (77)	279.6 (101)
BOB	0.8	23.4	1.8 (125)	29.9 (28)	3.1 (288)	55.2 (136)	3.9 (388)	95.0 (306)

As compared to room temperature measurements, after storage at -35°C, mean flow rate was lower with the O_2PAK. The duration of operation was longer, but the total oxygen was not markedly different. The mean flow rate and total oxygen volume were lower with the TraumAid, but the duration of operation was unchanged. The mean flow rate and total oxygen volume were slightly higher with the BOB, but the duration of operation was less.

After storage at 60°C, mean flow rate was higher with the O_2PAK, but the total oxygen volume and duration of operation were lower as compared to room temperature measurements. Mean flow rate was higher with the TraumAid, but total oxygen volume and duration of operation were lower. Mean flow rate was higher with the BOB, total oxygen volume was unchanged, but duration of operation was less. Table 3 shows mean flow rate, mean total oxygen volume, and mean duration of the devices at all test conditions.

The highest surface temperature with each device was 172°F with the O_2PAK, 167°F with the TraumAid, and 173°C with the BOB. These temperatures occurred at or near the time oxygen generation ceased. In addition to oxygen production, analysis of gas composition using the mass spectrometer showed that the BOB produced trace amounts of carbon monoxide, argon, carbon dioxide, and hydrogen (Figure 4). The O_2PAK produced trace amounts of hydrogen peroxide (Figure 5). The TraumAid produced trace amounts of hydrogen peroxide and also carbon dioxide, which increased at the end of the duration of operation (Figure 6).

Table 3. Mean (± SD) Flow Rate, Total Oxygen Volume, and Duration of Operation at Sea Level at Room Temperature, at Altitude, and after Storage at Temperature Extremes

Condition	Mean Flow (Lpm ± SD)	Mean O_2 Volume (L ± SD)	Mean Duration (min ± SD)
O_2PAK			
Room temp/sea level	6.5 ± 2.6	181.3 ± 37.8	27.6 ± 2.3
8,000 ft	7.6 ± 2.7	220.5 ± 6.3	28.9 ± 1.6
16,000 ft	10.5 ± 3.8	301.0 ± 1.4	28.5 ± 0.9
22,000 ft	14.4 ± 5.2	421.3 ± 19.1	29.1 ± 1.8
-35°C	5.5 ± 1.6	188.5 ± 10.6	33.0 ± 2.0
60°C	7.9 ± 2.9	179.2 ± 10.6	22.6 ± 0.6
Traumaid			
Room temp/sea level	5.6 ± 2.8	139.2 ± 36.2	24.7 ± 0.4
8,000 ft	5.6 ± 3.4	152.9 ± 24.2	27.2 ± 1.6
16,000 ft	8.8 ± 5.6	222.2 ± 7.0	26.9 ± 1.6
22,000 ft	9.9 ± 6.7	279.6 ± 32.1	31.2 ± 1.3
-35°C	3.7 ± 2.6	96.6 ± 30.5	24.0 ± 7.9
60°C	6.5 ± 3.5	122.2 ± 9.4	18.7 ± 0.2
BOB			
Room temp/sea level	0.8 ± 1.0	23.4 ± 5.6	28.6 ± 4.3
8,000 ft	1.8 ± 1.5	29.9 ± 5.1	16.6 ± 3.0
16,000 ft	3.1 ± 2.9	55.2 ± 15.7	17.5 ± 2.1
22,000 ft	3.9 ± 3.1	95.0 ± 28.7	20.3 ± 2.7
-35°C	1.5 ± 1.0	36.3 ± 4.5	24.0 ± 3.0
60°C	1.7 ± 1.2	34.2 ± 2.3	19.2 ± 1.2

5.0 DISCUSSION

5.1 POCs

Oxygen concentrators were first employed as an alternative for compressed oxygen for use in long-term oxygen therapy in the home in the late 1970s. The devices were an attractive alternative due to the ability to supply unlimited oxygen, lower cost, and improved logistics compared to oxygen cylinders. Early concentrators were large and heavy, weighing as much as 65 kg. Six of these early devices (DeVilbiss DeVO2, Rimer-Alco Dom 10, Mountain Medical Econo 2, Ventronics Hudson 6200, Dragerwerk Permox, and Cryogenic Associates Roomate) were evaluated at continuous flows of 1-4 liters by Johns et al. [5], who found that all the devices at 1 and 2 Lpm produced oxygen concentrations of >90% but began to fall at 3 Lpm. All the devices produced oxygen concentrations >90% at the 4-Lpm setting. Gould et al. [6] also conducted a study using three of the same concentrators as Johns (Mountain Medical Econo 2, DeVilbiss DeVO2, Cryogenic Associates Roomate) in addition to Mountain Medical Mini 02 and Oxygen Enrichment Company OE-4E, producing similar results. Oxygen concentrators have also shown to be an effective and economical substitute for compressed oxygen cylinders in remote high-altitude areas [7,8].

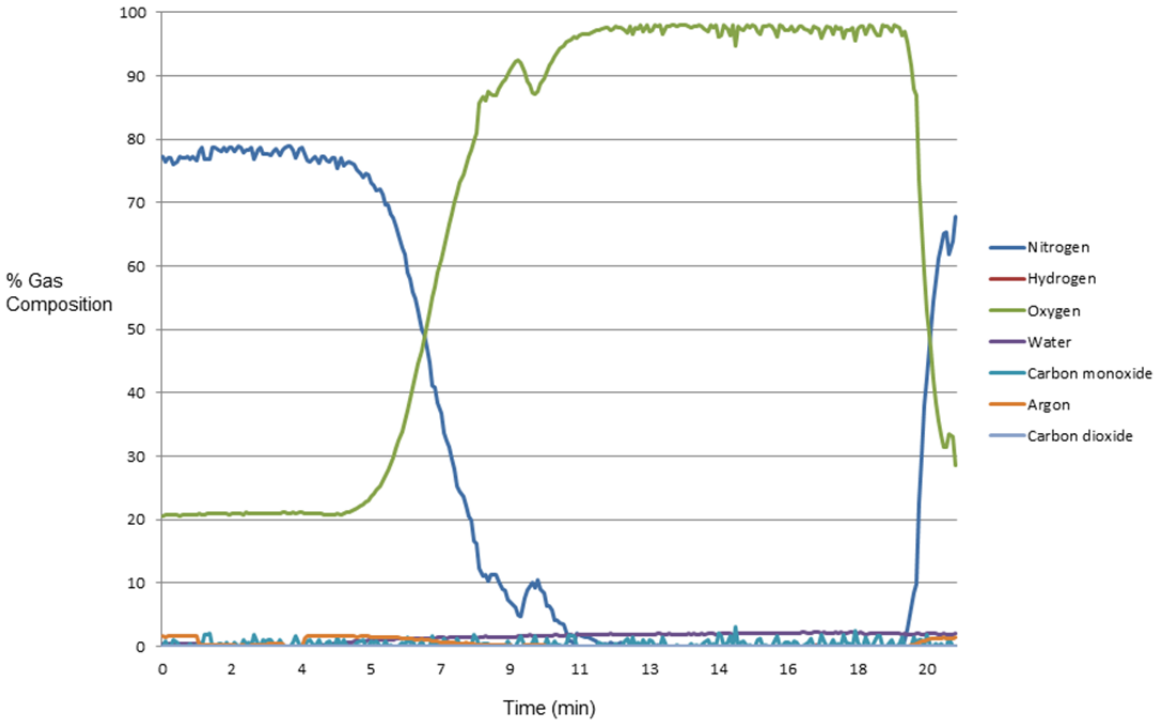

Figure 4. Gas composition of the BOB

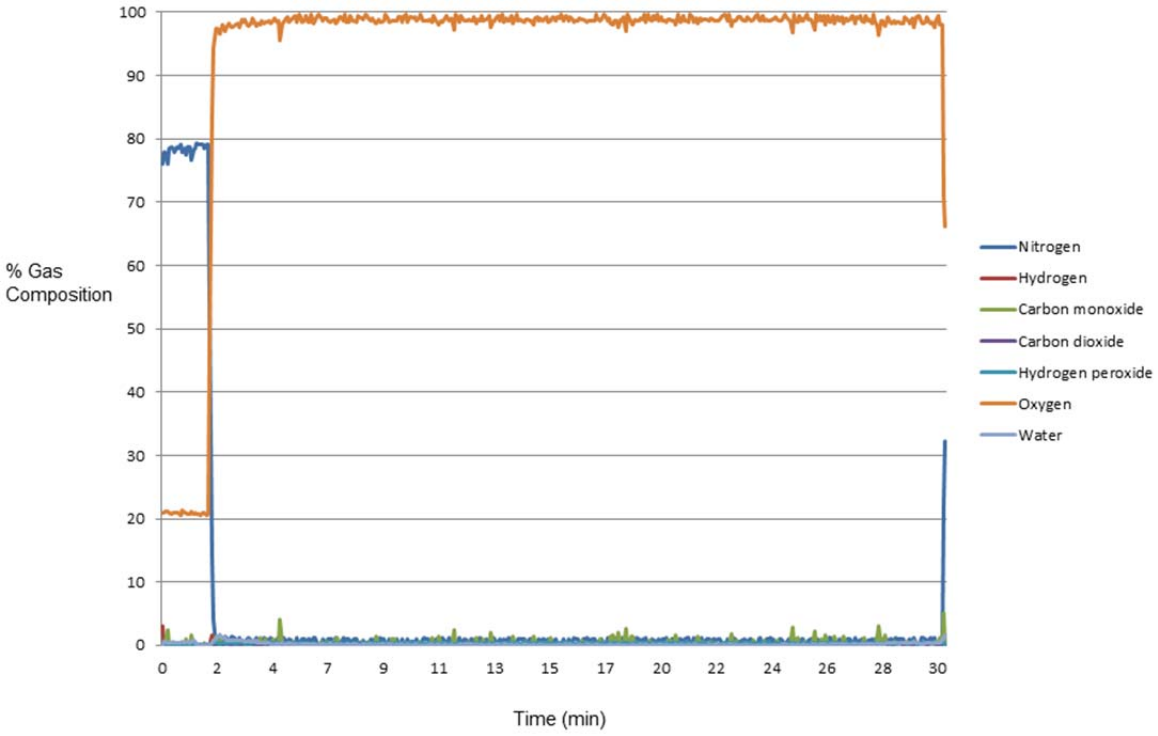

Figure 5. Gas composition of the O_2PAK

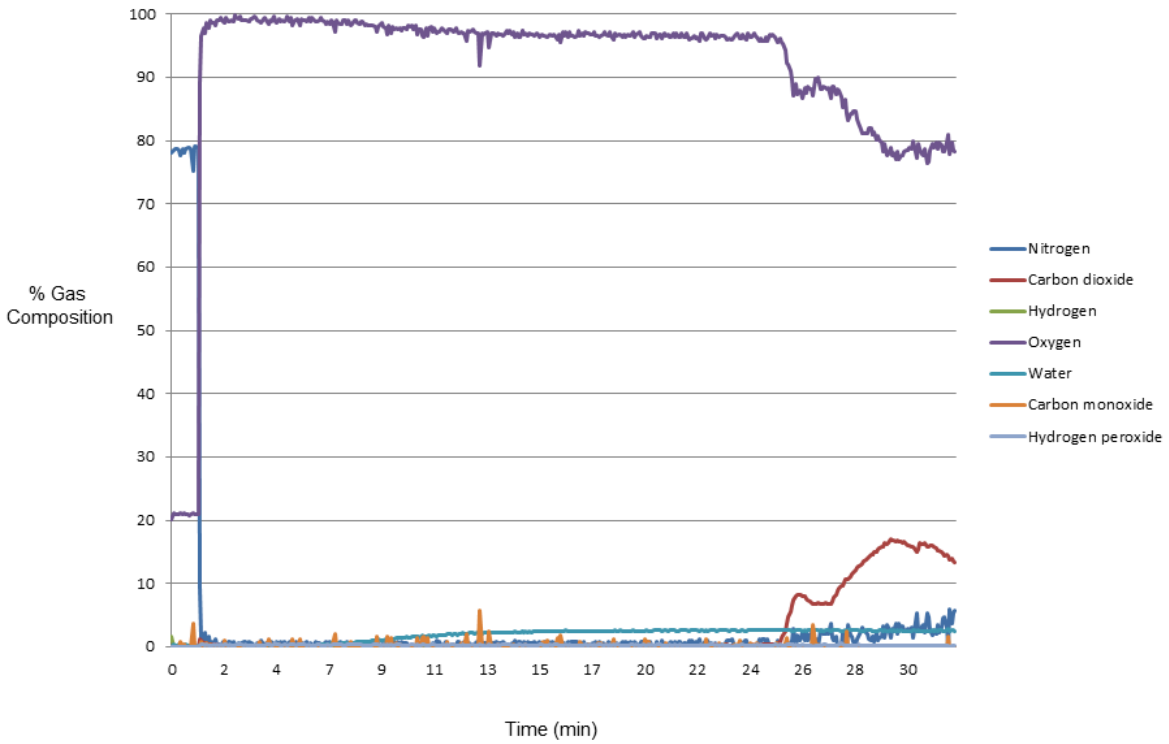

Figure 6. Gas composition of the TraumAid

Although these early concentrators performed adequately as stationary units in the home, they were too large for ambulatory use, so smaller cylinders were used for this purpose. POCs emerged in 2000 that were smaller, lighter devices with optional battery operation capable of producing up to 3 Lpm of continuous flow, making ambulation possible without switching to a cylinder [9]. Fischer et al. [10] conducted a study in an altitude chamber with volunteers having chronic obstructive pulmonary disease using five commercially available Federal Aviation Administration approved POCs (Invacare XPO2,Invacare, Elyria, OH; Freestyle AirSep C, Buffalo, NY; Evergo Philipps Healthcare, Hamburg, Germany; Inogen One, Inogen, Goleta, CA; Eclipse 3,Chart Industries, Ball Ground, GA) using bolus mode or, if not available, continuous flow mode at a simulated altitude of 2,650 meters (8,694 feet). The authors found that each POC was able to provide enough oxygen to the subjects to increase partial pressure of oxygen ≥10 mmHg. POCs have also been evaluated as the oxygen source for chronic obstructive pulmonary disease patients during a 6-minute walk test and were found to be a suitable alternative to portable oxygen cylinders or liquid oxygen for ambulation [11,12]. Rodriquez et al. recently performed a bench study of using a POC as the primary oxygen source for a portable ventilator that could be used during transport. The study showed that the integrated system was capable of producing an FiO_2 of up to 0.7 during selected settings [13].

Our study is the first to evaluate the performance of POCs at altitudes above normal commercial airline cabin altitude and after storage at extreme temperatures. With the exception of the Eclipse, the flow rates and bolus volumes were within or slightly less than the reported range. These differences are not clinically significant. The iGo would not operate at the two highest test altitudes, which were above the altitude limit stated in the owner's manual. The Eclipse and SAROS operated above the operator's manual stated altitude limit. The POCs are

designed to deliver a total volume 3 liters of oxygen/min, whether in bolus mode or continuous flow mode. When the combination of respiratory rate and set bolus volume exceeds the 3-liter threshold, the Eclipse and SAROS mitigate the effect by decreasing the bolus volume, while the iGo skips breaths to maintain an acceptable FiO_2. Our study design did not go above the reported maximum respiratory rate for any bolus volume with the SAROS and iGo. The maximum bolus volume for these two devices was 96 mL and 84 mL, respectively, and was 192 mL with the Eclipse. To maintain an FiO_2 in the specified range, at a respiratory rate of 20 breaths/min with the 192-mL bolus and a respiratory rate of 30 breaths/min with the 128-, 160-, and 192-mL bolus, the Eclipse decreases the bolus size. This strategy maintained the FiO_2 at sea level/room temperature and all altitudes but not after storage at temperature extremes. The measured FiO_2 range was 83% – 86% but the bolus volumes were 1% – 13% larger after temperature extreme storage, which may help to explain the lower FiO_2. The storage temperatures may have affected the device's ability to effectively regulate the bolus volume and/or generate the target oxygen concentrations at the higher bolus volume settings. Although the liter flow with the iGo in continuous flow mode after storage at -35°C was within the reported range, the FiO_2 was 15% – 20% lower than at room temperature, demonstrating the effect of extreme cold temperatures on oxygen generation during continuous flow mode. The POCs were tested at altitudes greater than recommended in the operator's manual. While the iGo ceased to operate at 16,000 feet, the Eclipse and SAROS operated within specified performance ranges at all study altitudes.

5.2 COGs

Chemical oxygen generation is not a new concept. It is the method by which Joseph Priestly discovered oxygen during his work with mercuric oxide. Priestly published his findings in 1775 [14]. In 1902, the Lancet reported on Kamm's oxygen generator invention for medical use. The device used chlorate cakes and manganese oxide and, when heated by a spirit lamp, produced approximately 4 ft^3 of oxygen before needing to be replenished with ingredients [15]. More recently, there has been interest in employing this technology in areas where providing oxygen in cylinders or in liquid form is logistically difficult or economically prohibitive such as during combat casualty care, disaster situations, and in extreme rural environments in undeveloped countries.

To our knowledge, our study is the first to evaluate COGs at altitude and temperature extremes. Pollock and associates evaluated emOx and SysO2 COGs at sea level [16,17]. These devices were similar to the BOB included in our study and were similar in performance. No other publications of COG evaluations were found. The O_2PAK and TraumAid were similar in design and function, but the O_2PAK produced more oxygen volume due to a higher flow rate and duration of operation at all conditions. After storage at -35°C, the output of these two devices decreased but increased after storage at 60°C as compared to room temperature. Oxygen is produced by an exothermic reaction, and the temperature of the device ingredients at time of ignition and throughout operation affects the device output. The total output of the BOB was much less than the O_2PAK and TraumAid due to a slower reaction (Figure 7). Peak flow occurred toward the end of the reaction with the BOB as compared to the beginning of the reaction with the other two COGs. Unlike the O_2PAK and TraumAid, the BOB was unaffected by storage at temperature extremes. The device uses two dry, granular chemicals, which were stored at temperature extremes, and tap water as a catalyst, which was not stored with the

chemicals. This would be the practice during use in the field. The consistent water temperature may have allowed for a reaction that was comparable to the performance at room temperature.

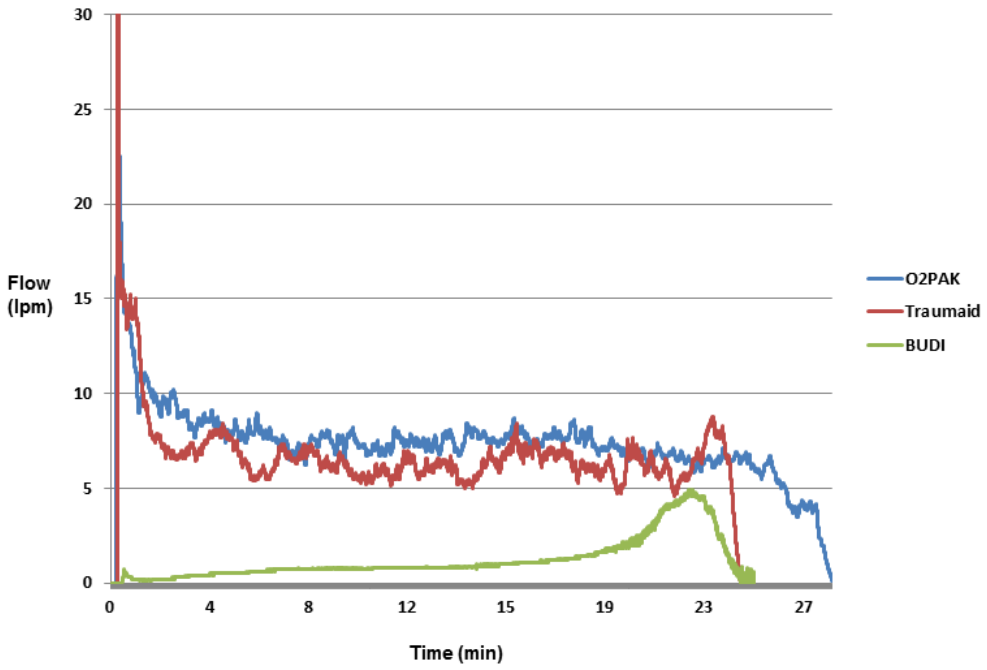

Figure 7. Sample run with all three COGs showing flow rates and duration of operation

Oxygen volume and flow rate increased with increases in altitude with each device. With the O_2PAK and TraumAid, the atmospheric pressure impacts the rate of creation and/or expansion of the gas but without change in duration of operation. For a given mass of gas produced, a larger volume will be produced at altitude. Gas is dissolved in a liquid with the BOB, and at altitude Henry's law may explain the increase in oxygen production and flow. Henry's law states that the amount of gas dissolved in a liquid is directly proportional to the partial pressure of the gas above the surface of the solution. When ambient pressure decreases at altitude, the dissolved oxygen is released in greater quantity and, due to the impact of altitude on gas density, a larger volume will be released.

Due to device design and use of dry chemicals to create oxygen, both the O_2PAK and TraumAid can be operated in any orientation. The devices are small and easy to use, requiring the pulling of two pins to activate and start oxygen flow. The BOB is more time consuming to prepare for use. The device requires mixing of two dry chemicals with tap water and must be operated in an upright position, either sitting on the ground or hanging by the handle, due to the use of water as the catalyst, which would spill and/or clog the oxygen outlet. Additionally, the cap filled with desiccant through which the oxygen exits the bag is heavy and during operation tends to fall over and crimp the bag, diminishing or ceasing the flow of oxygen. Modifications to positioning of the bag must be made to mitigate this problem. There are safety concerns related to the external temperatures during operation of all three COGs. The surface temperature of the devices reached 167°F – 173°F, which could easily cause burns if positioned against a patient. Based on the total volume of oxygen produced at sea level, the cost per liter was $3.73 for the O_2PAK, $6.44 for the TraumAid, and $1.73 for the BOB. Although there were trace amounts of

gases other than oxygen produced with the COGs, the amounts were too small to be of concern, with the exception of the rising carbon dioxide at the end of the chemical reaction with the TraumAid. The flow rate during this time was <1 Lpm, so it is unclear if the volume of carbon dioxide produced would be a risk to a patient. To mitigate any possible negative effects to the patient, change the COG canister before the device is completely exhausted to ensure excess carbon dioxide is not inhaled.

6.0 CONCLUSIONS

POCs and COGs have been proposed as alternatives to liquid and pressurized gaseous oxygen systems in far forward military operations and in disaster and mass casualty scenarios. The austere environments in which the devices may be deployed may have an effect on performance. Storage at extremely cold temperatures had the greatest negative effect on the performance of the POCs. Allowing additional time for the devices to acclimate to room temperature before startup may improve device performance. POCs should not be operated at altitudes above that stated in the operator's manual.

POCs are an attractive option due to their small size, but the output is finite, performance is unpredictable at altitude and temperature extremes, and they may be cost prohibitive to use on a larger scale. Because of its limited flow rate and total oxygen yield, the BOB does not supply an adequate amount of oxygen to be useful in emergency situations, and the logistics of maintaining the system is cumbersome. As with the COGS, storage at extremely cold temperatures decreased the output of the O_2PAK and TraumAid. All the devices tested may benefit from a longer time to acclimate to room temperature before use. Since the intended use of all these devices for military and disaster operations may require that both POCs and COGs be stored and operated in environments that are outside the manufacturers' published thresholds, users must be aware of the limitations of each and mitigate as much as possible.

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LIST OF ABBREVIATIONS AND ACRONYMS

BOB	BUDI Oxygen Bag
CI	confidence interval
COG	chemical oxygen generator
FiO_2	fraction of inspired oxygen
POC	portable oxygen concentrator
SD	standard deviation